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IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-215

UNITED STATES OF AMERICA, *Petitioner*

v.

JOHN R. PARK

On Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

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BRIEF *AMICUS CURIAE* OF THE NATIONAL ASSOCIATION OF FOOD CHAINS

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INDEX

	Page
STATEMENT OF INTEREST	1
SUMMARY OF CASE	4
SUMMARY OF ARGUMENT	6
ARGUMENT	8
The Decision of the Court of Appeals Is Consistent with This Court's Decision in *United States* v. *Dotterweich*	8
Criminal Liability of a Supervisory Employee for Violations of the Act Must Be Based on Gross Negligence, Inattention in Discharging Corporate Duties or Other Acts of Commission or Omission Which Cause the Contamination of Food	13
The Decision of the Fourth Circuit Will Result in More Effective Compliance with the Act by Encouraging Greater Numbers of People To Become Involved in Sanitation Activities	18
CONCLUSION	24

CASES:

California v. *Robinson*, 370 U.S. 660 rehearing denied, 371 U.S. 905 (1962) 16

Morisette v. *United States*, 342 U.S. 246 (1952) 17

United States v. *Dotterweich*, 320 U.S. 277 (1943) ...5, 6, 7, 9, 10, 11, 12, 13, 15

United States v. *Park*, 499 F.2d 839 (4th Cir. 1974) 5, 6, 7, 8, 9, 11, 12, 13, 15, 16, 17, 18, 21, 23, 25

United States v. *Wiesenfield Warehouse Co.*, 376 U.S. 86 (1964) 17

Page

STATUTES:

Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. 301 *et seq.* 2, 3, 4, 6, 8, 10, 12, 15, 19, 20, 24, 25

Section 301(k), 21 U.S.C. § 331(k) 2

18 U.S.C. § 2 .....10, 12

MISCELLANEOUS:

Comptroller General of the United States, *Dimensions of Insanitary Conditions in the Food Manufacturing Industry* 23

J. HAGAN, A MANAGEMENT ROLE FOR QUALITY CONTROL, 62 (1968) 19

Joint Appendix, *United States* v. *Park,* (No. 74-215, cert. granted Nov. 11, 1974) — U.S. — (1975) 5

Note, *Criminal Responsibility for Pollution of the Environment,* 37 ALBANY L. REV. 62 (1972) 13

P. DRUCKER, MANAGEMENT, 400 (1974) 20

Sayre, *Criminal Responsibility for Acts of Another,* 43 HARV. L. REV. 689 (1930) 14, 15, 16

Voluntary Industry Sanitation Guidelines for Food Distribution Centers and Warehouses, prepared by NAFC, et al (1974) .....3, 19, 20, App. A

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STATEMENT OF INTEREST

The National Association of Food Chains, Inc. [hereinafter "NAFC"], submits this brief as *amicus curiae* because of the concern of its members with the matter before the Court. Both parties have given their consent to NAFC's participation, pursuant to Rule 42.2.

NAFC is a non-profit trade association whose approximately 200 members are engaged in the retail distribution of food and grocery products. The Association is composed of all the larger, most of the medium-sized and a cross-section of smaller food chains in the United States.

The members of the Association engage in numerous activities subject to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, including warehousing and distributing food products to individual stores. NAFC members are also extensively engaged in food processing activities such as the operation of dairies, bakeries, coffee plants, and canneries.

Members of NAFC have a substantial and continuing interest in the effective enforcement of the Federal Food, Drug and Cosmetic Act. It is to the obvious benefit of all food chains that the food which they purchase from suppliers and sell to customers is free from adulteration, handled under sanitary conditions and accurately labeled.

The case before the Court concerns the responsibility of top-level management for warehouse sanitation. In order to provide guidance to its members in this important area, NAFC has recently taken responsibility for coordinating the efforts of seven trade associations and the Food and Drug Administration of the Department of Health, Education and Welfare in the preparation and publication of Voluntary Industry Sanitation Guidelines for Food Distribution Centers and Warehouses. These guidelines are attached as Appendix A. The Guidelines indicate the continuing efforts which NAFC and its members have undertaken to achieve compliance with § 301(k) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 331(k).

The implications of this case, however, extend beyond the issue of warehouse sanitation and the application of § 301(k), 21 U.S.C. § 331(k). The decision in this case will have a direct impact on the extent of

criminal prosecution for all offenses under the Federal Food, Drug and Cosmetic Act [hereinafter "Act"]. As presented to the Court, the issue is whether or not an individual can be held criminally liable for a corporate violation of the Act where there is no evidence of his participation in the alleged violation.

NAFC does not question whether an individual employee should be subject to criminal sanctions under the Federal Food, Drug and Cosmetic Act, where through some act or omission on his part a food product is unlawfully adulterated or misbranded. Where, however, a corporate officer or other employee has diligently undertaken to establish and implement a comprehensive compliance program neither the statute nor prior cases require that he be convicted of a criminal offense. To the contrary, the underlying purpose of the Act, purity and accurate labeling of food, should encourage such comprehensive compliance. This purpose would be ill-served by a construction of the Act which would subject a company employee to criminal punishment for inadvertent, often unavoidable, violations without regard to the comprehensiveness of the compliance program which he has established or the diligence of his supervisory efforts.

NAFC's interest in this case, thus, derives from a basic conclusion that effective compliance with the Act will best be obtained by requiring a high standard of effort as evidenced, in part, by its warehouse sanitation guidelines. *See,* Appendix A. The Government's advocacy of an absolute criminal liability rule based solely on an individual's corporate position adds nothing to effective compliance and, in fact, may detract from it.

The decision of the United States Court of Appeals for the Fourth Circuit established a correct, practical, and equitable standard which will result in better compliance with the Federal Food, Drug and Cosmetic Act.

The decision of the Court of Appeals provides that an individual's criminal liability under § 303 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 333, must be based on his own acts or omissions which contribute to a violation. NAFC's members strongly urge that this standard be affirmed, both because it correctly interprets applicable law, and because it establishes a workable rule for compliance with the Act.

SUMMARY OF THE CASE

This action was initiated in the United States District Court for the District of Maryland by criminal informations against Acme Markets, Inc. [hereinafter "Acme"] and Acme's President, Respondent John R. Park. The informations were based on the presence of rodents in a portion of Acme's Baltimore warehouse. Acme, a large retail food chain employing approximately 36,000 persons in 874 retail outlets, has twelve main warehouses and four special warehouses.

The informations against Acme and Park contained five counts, four of them based on deficiencies noted during a Food and Drug Administration inspection in November-December 1971, and one based on a deficiency noted in a subsequent inspection in March of 1972. The corporate defendant, Acme, Inc., entered a plea of guilty to each of the five counts.

Prior to trial, Park filed a Motion for Bill of Particulars seeking the details of his alleged liability

for the violations. (Jt. App. at 10) The government responded to the motion by disclosing that the evidence would not show that defendant Park personally performed any of the acts described in the information, but that "the government's evidence will simply show that the defendant was a corporate officer who, under law, bore a relationship to the receipt and storage of food which would subject him to criminal liability under *United States* v. *Dotterweich,* 320 U.S. 277 (1943)." (Jt. App. at 14-15)

At Park's trial, the charge to the jury was given in substantially the form requested by the government and incorporated the same theory of liability set forth in the government's response to the motion for bill of particulars. After defining the elements of interstate shipment and unsanitary conditions, the trial court charged the jury to consider a third element:

> "Thirdly, that John R. Park held a position of authority in the operation of business of Acme Markets, Incorporated.
>
> "However, you need not concern yourself with the first two elements of the case. The main issue for your determination is only with the third element, whether the Defendant held a position of authority and responsibility in the business of Acme Markets." (Jt. App. at 61)

This portion of the charge to the jury, combined with other portions reflecting the view that criminal liability might exist without evidence of any wrongful action on the part of the Respondent, resulted in the Court of Appeals reversing. *United States* v. *Park,* 499 F.2d 839 (4th Cir. 1974).

In reversing Park's conviction, the Court of Appeals concluded:

> [A] finding of guilt must be predicated upon some wrongful action by Park. That action may be gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission of omission which would "cause" the contamination of the food. *United States* v. *Park, supra,* 499 F.2d at 842.

The Court of Appeals also concluded:

> It is the defendant's relation to the criminal acts, not merely his relation to the corporation, which the jury must consider; 21 U.S.C. § 331 is concerned with criminal conduct and not proprietary relationships. *United States* v. *Park, Supra,* 499 F.2d at 841.

The government petitioned for a writ of certiorari claiming that individual guilt may be based on "constructive participation," a test to be applied solely on the basis of the individual's formal duties and official responsibilities (Petitioner's Brief for Certiorari at 12).

SUMMARY OF ARGUMENT

I.

The decision of the Court of Appeals correctly interprets the applicability of criminal sanctions under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.,* and is consistent with the decision of the Court in *United States* v. *Dotterweich, supra.* Justice Frankfurter's decision in *Dotterweich* concludes that the Federal Food, Drug and Cosmetic Act is part of a class of legislation which ". . . dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing," *United States* v. *Dotterweich, supra,* 320 U.S. at 281. A person who violates this type of statute is subject to "strict" liability for

his violative act, whether or not he was aware that his action violated a regulatory standard. The Fourth Circuit correctly followed *Dotterweich* in concluding that while awareness of wrongdoing is not an element of the offense, Park could not be found guilty in the absence of "wrongful action" on his part. *United States* v. *Park, supra,* 499 F.2d at 841. *See* text 8-13, *infra.*

II.

Criminal liability for the acts of others must be based on the accused's participation in a criminal act, or his aiding and abetting in its commission. *See,* text 13-16, *infra.*

The government's position erroneously states the law by confusing the element of "awareness of wrongdoing" which need not be proved, with the element of "wrongful action" which must be found to hold Park as President of the company criminally liable. Until the government demonstrates that Park "participated" in causing a violation of the Act, he is not within the class of persons who may be subject to the Act's strict liability. The net effect of the government's position is to advocate that Park be held criminally liable by virtue of his office alone, which is a fundamental misconstruction of the Court's reasoning in *Dotterweich.* The government and the district court have erred in applying strict liability to Park without requiring proof of the casual connection, if any, between Park and the alleged violations. They have, thus, erroneously ignored controlling and traditional requirements of aiding and abetting which must be proved to establish vicarious participation in the wrongful action. *See* text 16-24, *infra.*

III.

The decision of the Court of Appeals would lead to more effective compliance with the Federal Food, Drug and Cosmetic Act than can be achieved through the standard urged by the government. The Court of Appeals has provided an incentive for managers to become responsibly involved in complying with the Federal Food, Drug and Cosmetic Act, and to build affirmative records demonstrating their care and diligence in exercising such responsibility. The government's standard would deter the involvement of corporate officials in compliance programs.

The decision of the Court of Appeals would make diligence a defense, while the standard of constructive participation urged by the government would make mere corporate position a crime. Successful compliance with the Federal Food, Drug and Cosmetic Act requires broad-scale and positive involvement of company managers and employees which would be encouraged by the Court of Appeals' standard. *See* text 17-24, *infra*.

ARGUMENT

I. THE DECISION OF THE COURT OF APPEALS IS CONSISTENT WITH THIS COURT'S DECISION IN *UNITED STATES v. DOTTERWEICH*.

The Court of Appeals properly recognized that:

> . . . For an accused individual to be convicted, it must be proved that he was in some way personally responsible for the act constituting the crime. The Supreme Court recognized this in *Dotterweich:* "The offenses committed . . . by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws

> . . ." *United States* v. *Park, supra,* 499 F.2d at 841 (4th Cir. 1974).

The Court of Appeals cited further language from *Dotterweich* in support of its decision:

> . . . To use the language of *Dotterweich,* "under Section 301 [21 U.S.C. § 331], a corporation may commit an offense and all persons who *aid and abet* its commission are equally guilty." *Id.* (Emphasis supplied by Court of Appeals.)

The government has relied on *Dotterweich* throughout its prosecution of Park. *Dotterweich* has been cited as authority by the government in its response to Park's motion for bill of particulars, its request for a charge to the jury and its petition for a writ of certiorari and its brief on the merits. The position enunciated by the government and incorporated by the district court in its jury charge is a misinterpretation of *Dotterweich*.

The government erroneously ignores the distinction set forth in *Dotterweich* between the "strict" liability for violations of the Federal Food, Drug and Cosmetic Act and "vicarious" liability of individuals for these violations. Strict liability is applied where awareness by the accused that his action was wrongful is not an element of the crime. Justice Frankfurter characterized the Federal Food, Drug and Cosmetic Act as a statute embodying this type of liability:

> . . . Such legislation dispenses with the conventional requirement for criminal conduct—awareness of wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in a responsible relation to a public danger. *United States* v. *Dotterweich, supra,* 320 U.S. at 281.

Although the Federal Food, Drug and Cosmetic Act establishes a standard of strict liability for determining whether individuals are criminally liable, this standard was carefully limited by Justice Frankfurter to individuals ". . . standing in a responsible relation to a public danger." *United States* v. *Dotterweich, supra,* 320 U.S. at 281.

While Mr. Justice Frankfurter held that an individual who has no "awareness of wrongdoing" could be convicted of violating the Federal Food, Drug and Cosmetic Act, he carefully defined those who might be subject to this strict liability as persons having the same causal relationship to the violation as described in section 322 of the penal code, 18 U.S.C. § 550 (1943) later codified in 18 U.S.C. § 2. *United States* v. *Dotterweich, supra,* 320 U.S. at 281 (1974).

Standards of liability for aiders and abetters in federal crimes are defined in 18 U.S.C. § 2:

> "(a) Whoever commits an offense against the United States or aids, abets, counsels, commands, induces or procures its commission is punishable as a principal.
>
> (b) Whoever willfully causes an act to be done which if directly performed by him or another would be an offense against the United States, is punishable as a principal."

In *United States* v. *Dotterweich, supra,* the defendant had a close causal relationship to the violations charged since the defendant had *direct* supervisory responsibility over the *physical* acts which resulted in the violation. Joseph Dotterweich admitted personal involvement with and oversight of all the activities of Buffalo Pharmacal Company, Inc., the corporate de-

fendant.[1] The language of the *Dotterweich* decision which concluded that "awareness of wrongdoing" is not a necessary condition precedent for criminal conviction under the Federal Food, Drug and Cosmetic Act is addressed to the defendant's strict liability for acts in which he participated, not to his vicarious liability for acts in which he did not participate.

Dotterweich cannot be interpreted, as it has been by the government, to extend criminal liability to individual employees, absent any evidence of their personal participation in a violation of the Federal Food, Drug and Cosmetic Act. The Federal Food, Drug and Cosmetic Act imposes strict liability only on those who participate in violating the Act; it does not impose a unique standard of vicarious liability, absent aiding and abetting as defined in 18 U.S.C. § 2.

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[1] The Record which was before this Court in Dotterweich shows that not only was Mr. Dotterweich responsible for every aspect of the corporate defendant's busienss, but also that he testified in a manner which emphasized his personal responsibility. *See,* Appellant's Brief at 12, *United States* v. *Park,* 499 F.2d 839 (4th Cir. 1974) which states in pertinent part:

The violations charged in Dotterweich arose from two shipments of digitalis alleged to be less potent than required by law and a shipment of pills alleged to be misbranded. The evidence showed that the corporate defendant had been "created" by Dotterweich, in the words of defense counsel (R. 63), was owned by him, had approximately 26 employees, working on one floor of an office building, with Dotterweich as President, "General Manager," and the only supervisor. During the testimony by Dotterweich, his counsel almost invariably used the word "you" to refer to actions taken by other employees who worked under Dotterweich's supervision (R. 128, 141, 142). On cross examination, Dotterweich admitted that, "When I am in the place, I am in charge," and that he was "the boss," and that he must have been in charge on a day when one of the challenged shipments went out since he had signed a letter that day in his capacity as "General Manager" (R. 143-144).

The decision of the Court of Appeals in the present case is carefully consistent with *Dotterweich*. It explains that "strict" liability for violations of the Act is not at issue, *United States* v. *Park*, 499 F.2d *supra*, 840, n.2, and addresses the separate question of whether the charge to the jury in the District Court properly stated the law as to Park's liability as president and chief executive officer of Acme. The Court of Appeals found the charge incorrect since it would have allowed the jury to find Park guilty solely on the basis of his ". . . position of authority and responsibility in the business of Acme Markets . . . even though he had not 'personally participated in the situation'." *United States* v. *Park, supra*, 499 F.2d at 840.

The Court of Appeals properly perceived that ". . . the Government has confused the element of 'awareness of wrongdoing' with the element of 'wrongful action'; *Dotterweich* dispenses with the need to prove the first of those elements but not the second." *United States* v. *Park, supra* 499 F.2d at 841. The Court of Appeals further reasoned that, ". . . It is the defendant's relation to the criminal acts, not merely his relation to the corporation, which the jury must consider; 21 U.S.C. § 331 is concerned with criminal conduct and not proprietary relationships." *Id.*

The Court of Appeals correctly reversed Park's conviction since the jury could have based its verdict on Park's corporate position without considering his participation in the violative acts. The Court of Appeals' reversal is in harmony with the Court's decision in *Dotterweich*, which eliminated the need to prove awareness of wrongdoing, but which did not eliminate

the need to prove the accused's causal participation in the wrongdoing.

II. CRIMINAL LIABILITY OF A SUPERVISORY EMPLOYEE FOR VIOLATIONS OF THE ACT MUST BE BASED ON GROSS NEGLIGENCE. INATTENTION IN DISCHARGING CORPORATE DUTIES OR OTHER ACTS OF COMMISSION OR OMISSION WHICH CAUSE THE CONTAMINATION OF FOOD.

The basic issue presented by this case is the legal standard governing criminal liability of supervisory employees for violations of the law committed by subordinates. The government contends that a supervisory employee may be convicted for a violation occurring anywhere within the company on the basis of his position of authority. The Fourth Circuit holds that a supervisor may be found guilty only where he has participated in wrongful action.

The position of the government fails to provide a standard which juries can use in their deliberations.[2] On the other hand, the position of the Fourth Circuit provides a workable and legally sound standard for instructing juries on the possible criminal liability of company officers.

The present case involves the criminal liability of a general supervisor for the acts of subordinates. It is the type of liability which requires a causal connection between the supervisor's act and the alleged violation.[3] If supervisors are to be prosecuted under

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[2] The government's position is based on a fundamental misconception regarding the criminal responsibility of one individual for the acts of another. Such liability is "vicarious" and yet the government asserts that, "While the liability created by the 1938 Act is strict, it is not vicarious." (Brief for the Government at 14.)

[3] The desirability of holding supervisory officials vicariously liable for corporate violations of environmental standards is examined at length in Note, *Criminal Responsibility for Pollution of the En-*

section 301 of the Act, those prosecutions must be subject to the general standards for the imposition of criminal liability. These standards as embodied in the

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vironment, 37 ALBANY L. REV. 61 (1972). That article discusses Dotterweich's imposition of individual criminal liability for violations of the Federal Food, Drug and Cosmetic Act and advocates a similar standard for environmental legislation. The article goes on to describe the existing standard for vicarious liability as follows:

> The general rule is that an official will not be criminally liable for the acts of others within the corporation unless he participates in the act or aids and abets the criminal activity—3 Fletcher Cyc. Corp. § 1348 (1965); *State* v. *Flahe*, 83 S.D. 655, 165 N.W. 2d 55 (1969); *Clifton* v. *State*, 51 Del. 339, 145 A 2d 392 (1958); *State* v. *Pincus*, 41 N.J. Super. 454, 125 A 2d 420 (1956); *Hartson* v. *People*, 125 Colo. 1, 240 P 2d 907 (1952). 37 ALBANY L. REV. 61, 70.

The general rule recommended in this Note is compatible with the standard proposed by the Fourth Circuit. United States v. Park, 499 F.2d 839. (4th Cir. 1974) *See also* Sayre, *Criminal Responsibility for Acts of Another*, 43 HARV. L. REV. 689, 702-704 (1930). Sayre noted the importance of finding "causation" in those areas where criminal liability was based on the acts of another:

> "Vicarious liability is a conception repugnant to every instinct of the criminal jurist. It is not surprising, therefore, that courts today as a general rule . . . make criminal liability exclusively dependent upon causation. Causation may be proved either (1) by authorization, procurement, incitation or moral encouragement, or (2) by knowledge plus acquiescence. Apart from exceptional groups of cases . . . the law may be summarized as follows:
>
> (1) If the defendant can be shown himself to have counseled, procured, commanded, incited, authorized, or encouraged the commission of the particular act which forms the subject of the prosecution, all courts agree in holding him criminally liable, even though the agent committed the act through a different instrumentality, or at a different time, or in a different place from that ordered or authorized.
>
> (2) Where the defendant has neither authorized nor consented to the particular criminal act, even though he has authorized the general business in the course of which the act was committed, the defendant may be civilly, but is not, except as under (3), criminally, liable.
>
> (3) On the other hand, even if the particular criminal act has not been authorized or consented to, if it grows out of and is the proximate consequence of one that has been authorized or procured, the defendant is criminally liable, whether or not the agent is acting in the course of the defendant's business." Sayre, *Criminal Responsibility for Acts of Another*, 43 HARV. L. REV. 689, 702-704 (1930).

Court's decision in *Dotterweich* and further developed by Court of Appeals require a "responsible relationship" or causal connection between the wrongful act and the individual charged under the Act.

The decision of the Court of Appeals correctly states the law governing the vicarious liability of an individual employee for violations of the Federal Food, Drug and Cosmetic Act:

> . . . For an accused individual to be convicted it must be proved that he was in some way personally responsible for the act constituting the crime. *United States* v. *Park, supra,* 499 F.2d at 841.

The Fourth Circuit further concludes:

> Upon a subsequent trial the jury should be instructed that a finding of guilt must be predicated upon some wrongful action by Park. That action may be gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission which would "cause" the contamination of the food. *United States* v. *Park, supra,* 499 F.2d at 842.

The Court of Appeals correctly declared that, ". . . The question of causation is to be distinguished from that of intent." *United States* v. *Park, supra,* 499 F.2d at 842, n.7.

In holding that a supervisor's wrongful action must be causally related to a violation of the Federal Food, Drug and Cosmetic Act, before an individual may be held criminally responsible, the Fourth Circuit has enunciated a legally sound standard to be applied to cases involving "vicarious" liability. In the present case there is no allegation that Mr. Park counseled, procured, commanded, incited, authorized or encouraged the commission of the particular acts which forms the subject of the prosecution.[4] If Park is to be held vicariously liable, then it must be because his conduct falls within the category of vicarious criminal liability where:

> ". . . [E]ven if the particular criminal act has not been authorized or consented to, if it grows out of and is the proximate consequence of one that has been authorized or procured, the defendant is criminally liable . . ."[5]

The Fourth Circuit concludes that "gross negligence and inattention" are the kind of wrongful action upon which vicarious liability may be predicated; thus, finding supervisory employees responsible only for the "proximate consequences" of their actions. *United States* v. *Park, supra,* 499 F.2d at 842.

The standard of liability urged by the government is based solely upon the supervisory position of the defendant.[6] However, while the government suggests that this is not the standard it is advocating,[7]

[4] *See* Sayre, Note 3, *supra,* at 702.

[5] *See* Sayre, Note 3, *supra,* at 703-704.

[6] This standard based on corporate office-holding comes very close to the type of "status" offense held unconstitutional in California v. Robinson, 370 U.S. 660, rehearing denied 371 U.S. 905 (1962).

[7] "The majority of the Court of Appeals believed the government to be arguing 'that the conviction may be predicated solely upon a showing that the defendant, Park, was the President of the offending corporation'." (Brief for Government at 11.)

the only additional element which the government apparently views as a prerequisite for a conviction is the existence of a violation on the part of the corporate employer. The government apparently concedes that an accused may demonstrate his lack of power and responsibility as defense to alleged liability.[8]

The proper standard for determining the liability of a supervisor must turn on his causal connection to a wrongful act as enunciated by the Fourth Circuit. The *per se* standard of guilt by position urged by the government is contrary to law. The standard of criminal liability adopted by the Fourth Circuit, is correct and should be affirmed.

III. THE DECISION OF THE FOURTH CIRCUIT WILL RESULT IN MORE EFFECTIVE COMPLIANCE WITH THE ACT BY ENCOURAGING GREATER NUMBERS OF INDIVIDUALS TO BECOME INVOLVED IN SANITATION ACTIVITIES.

The standard for imposition of criminal liability established by the Court of Appeals will result in more effective compliance with the Federal Food, Drug and

[8] Brief for Government at 14. *See,* United States v. Wiesenfield Warehouse Co., 376 U.S. 86, 91 (1964). *See also,* Morisette v. United States, 342 U.S. 246 (1952), wherein Mr. Justice Jackson noted the limited applicability of strict liability to public welfare offenses. Mr. Justice Jackson raises the implication that strict liability is only appropriate where the accused has failed in a duty which he could reasonably be expected to perform.

> . . . The accused, if he does not will the violation, usually is in a position to prevent it with no more care than society might reasonably expect and no more exertion than it might reasonably exact from one who assumed his responsibilities. 342 U.S. at 256.

Cosmetic Act than will the standard urged by the government. Successful compliance with the Federal Food, Drug and Cosmetic Act requires the extensive and positive involvement of many individual employees. The standard announced by the Court of Appeals is more likely to encourage such involvement than the standard urged by the government, since it provides an incentive for individual employees to establish an affirmative record showing due care and diligence in complying with the requirements of the Act. The decision of the Court of Appeals will make diligence a defense, while the standard of liability by office urged by the government will make the mere holding of corporate office a crime.

The net effect of the Court of Appeals decision is to encourage individual employees and supervisors to become involved with programs of compliance under the Federal Food, Drug and Cosmetic Act. This extensive involvement is particularly important in complying with the Act's sanitation requirements since optimal compliance entails complex activities which, in most companies, cannot be handled by a single employee or even by a small group of employees. The complexity of a good sanitation program is indicated by the Voluntary Industry Sanitation Guidelines for Food Distribution Centers and Warehouses.[9] The appendix to the Guidelines describes the commitment of personnel necessary for an effective sanitation program:

> To ensure product wholesomeness and proper sanitation, the food warehouse sanitation program must have the commitment of top management, must be implemented by operating supervision,

[9] Reprinted *infra* as Appendix A.

and must be supported by the entire food warehouse staff. Preventive sanitation—the performance of inspection, sanitation, building maintenance, and pest control functions designed to prevent insanitation in preference to correcting it—should be an important goal of food warehouse management and of food warehouse operations.

A program to ensure continued success in safeguarding the wholesomeness of food and in providing good sanitation will ordinarily include:

(1) An organizational chart showing chain of authority and responsibility.

(2) A flow diagram of receiving, storage, and shipping operations.

(3) Regular maintenance schedules.

(4) Regular sanitation programs.

(5) Regular pest control programs.

(6) An effective program of follow-up and control including reports to responsible executive officer(s)." Appendix A, *infra*, at 15a-16a.

An effective sanitation program must utilize the most modern techniques of management through quality control to systematically achieve product standards and eliminate defects. Management through quality control utilizes methodical inspection at various points in the manufacturing or distribution process to prevent defects and achieve higher quality standards than are obtainable by direct visual product inspection.[10]

[10] The genesis of quality control is described in J. HAGAN, A MANAGEMENT ROLE FOR QUALITY CONTROL, 62 (1968)

> "Quality control originated in inspection. So many defects were originally found in delivered products that inspection was established to screen good products from bad at the end

Preventive techniques, utilizing up-to-date methods of systematic quality control, are the best way to assure compliance with federal sanitation standards. The Voluntary Industry Sanitation Guidelines stress that "preventive sanitation" is preferable to the correction of insanitation and recommend regular maintenance schedules, sanitation programs and pest control programs, together with effective follow-up and reports to responsible executives. The management of this type of recommended sanitation program involves the coordination of a number of people. No one individual can personally sweep every floor or bait every rodent trap. The Court of Appeals by holding each individual liable for his own performance encourages individuals to become involved in compliance programs knowing that their individual responsibility for preventive activities must be diligently pursued.

The tasks of a manager have been defined by Peter Drucker, a leading authority on management techniques, to include: (1) setting objectives; (2) organizing to achieve those objectives; (3) motivating and communicating with employees; and (4) measuring the degree to which objectives are achieved and communicating those measurements to both subordinates and superiors.[11] All of these tasks are involved in the

of the production line, thus enabling the company to maintain an acceptable performance image and so continue to grow productively. Before long, when it became obvious that the rejected products represented an ever-increasing cost, inspection was extended to include points within the manufacturing process. This move was intended to prevent the manufacture of defective articles and was the start of quality control."

[11] P. DRUCKER, MANAGEMENT, 400 (1974).

management of a sanitation program. The objectives of meeting or exceeding federal sanitation standards are obvious. The organization necessary to achieve the objectives may take many forms. In every case, the success of that organization will depend upon the following integral factors: first, management's communication of program objectives to employees; second, employees' communication of barriers preventing the achievement of program objectives to management; third, on-going measurement of compliance progress.

Improved sanitation can only result from orderly and systematic management utilizing the latest quality-control techniques. The government, in describing courses of action open to Mr. Park, advocates procedures which are disorganized and unsystematic.[12]

[12] "There were a number of constructive actions [Mr. Park] should have taken. With the list of observations before him, he could have applied his own common sense to the situation and personally ordered corrective action. He could have, for instance, demanded that the warehouse be completely emptied and cleaned, that each lot of food be moved and checked thoroughly for rodents, and that the structure be thoroughly checked to make sure that all possible points of rodent entry be closed. Such measures are elementary methods of house cleaning.

"At the very best, respondent should have personally discussed with McCahan the list of observations item by item and ascertained precisely what McCahan would do about each. He could have demanded to know why the Baltimore facility had been allowed to deteriorate to the point that it had. He could have attempted to ascertain the amount of effort and money that would be necessary to insure that the premises would be cleaned up properly and offered McCahan whatever assistance was necessary. Any one or all of these things would have impressed upon McCahan the importance which he attached to the situation. He could also have instructed the appropriate corporate officials to utilize the resources necessary to remedy the situation. Certainly respondent could have followed up by calling McCahan and other corporate officials who handled sanitation problems to get personal briefings on the specific correc-

Even if a company employee took all of the uncoordinated measures suggested by the government, he would still be subject to criminal prosecution solely on the basis of his corporate position if any violative condition remained.

The decision of the Court of Appeals will have a salutary effect. Under that decision, an individual's failure to organize, communicate, or measure the success of sanitation efforts may constitute evidence sufficient to sustain a criminal conviction, while active efforts to improve sanitation will only create individual liability where such efforts causally contribute to violations of the Act.

Under the standard of liability by office urged by the government, an individual employee who takes part in communication and measurement of compliance is subject to criminal prosecution if any part of the compliance system fails, even where the failure occurs through no fault of the accused. This approach would deter individual employees from involving themselves in the communication and measurement process, which is necessary to achieve optimal sanitation standards. Orderly management requires the

tions being made. Indeed, given the fact that these same employees had already failed twice in the recent past, respondent could have retained a reputable outside consultant familiar with FDA requirements. Nor would it have been unreasonable for respondent to have personally visited the Baltimore warehouse to see for himself what progress, if any, was being made in correcting the situation. Finally, he could have closed the warehouse down unless and until he was personally satisfied that it had, beyond any doubt, been cleaned up. Given respondent's apathetic behavior, it is not surprising that the necessary steps were not taken and that many of the conditions went uncorrected until a criminal prosecution was instituted." (Brief for Government at 34, n.19)

active involvement of large numbers of employees. Active involvements is the government's own professed goal for the management of sanitation programs. Yet the standard of liability urged by the government would discourage involvement.

The Court of Appeals has correctly decided that the government's standard is not in accordance with settled doctrines of law. The government's standard is inherently unjust because it fails to distinguish between the criminal liability of an employee who exercises due care and diligence in carrying out his responsibilities and one who does not. The sole determinant of *per se* liability under the government's standard is whether any evidence of violation is discovered within an accused's formal scope of authority. No consideration is given to whether the accused had a role in causing that violation. Such an approach would provide an incentive to place responsibility for complying with the Federal Food, Drug and Cosmetic Act on the fewest possible employees rather than making such compliance an extensive, cooperative effort by many employees.

Although the government's policy of liability by office for Food and Drug Act violations can only be justified as a deterrent, there is no demonstration that this standard has been successful in the past.[13]

The Court of Appeals' decision, by requiring that the government prove that an individual act, or gross negligence, or inattention is causally related to the

[13] *See e.g.*, Comptroller General of the United States, *Dimensions of Insanitary Conditions in the Food Manufacturing Industry*, Report to Congress, No. B-164031(2) (Apr. 18, 1972).

violation, will encourage the greater involvement required for effective sanitation management. This potential for improved compliance is in furtherance of the Act's objectives and compels affirmation of the Court of Appeals' decision.

CONCLUSION

Therefore, the decision of the United States of Appeal for the Fourth Circuit should be affirmed.

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APPENDIX

APPENDIX A

VOLUNTARY INDUSTRY SANITATION GUIDELINES FOR FOOD DISTRIBUTION CENTERS AND WAREHOUSES

1974

Sponsored by:

ASSOCIATION OF INSTITUTIONAL DISTRIBUTORS
COOPERATIVE FOOD DISTRIBUTORS OF AMERICA
GROCERY MANUFACTURERS OF AMERICA
INTERNATIONAL FOODSERVICE DISTRIBUTORS ASSOCIATION
INTERNATIONAL FOODSERVICE MANUFACTURERS ASSOCIATION
NATIONAL-AMERICAN WHOLESALE GROCERS' ASSOCIATION
NATIONAL ASSOCIATION OF FOOD CHAINS

In cooperation with the
U. S. FOOD AND DRUG ADMINISTRATION

I. Foreword

These guidelines were prepared for receiving, handling, storage, and shipping of food and food products contained in retail and/or shipping containers at food distribution centers and food warehouse establishments, referred to as "food warehouses" throughout these guidelines. The term "food(s)" in these guidelines means foods and food products which are contained in retail and/or shipping containers, but includes items such as fresh produce received unpackaged or in partially open packages, which are subject to various specific additional portions of the guidelines.

The purpose of these guidelines is to promote receiving, handling, storage, and shipping of food and related items at such establishments in a manner that will assure the continued delivery of safe, sanitary, and wholesome foods to consumers.

It is further intended that conscientious adherence to the letter and spirit of these guidelines will not only minimize the chance of noncompliance with applicable governmental requirements for food sanitation, but will improve and maintain the overall effectiveness and quality of the practices by which foods are brought to the American consumer.

In this context, it is essential that management, including those directly responsible for any food warehousing activity, make provision for persons employed in a food handling capacity to receive the degree of training, emphasis, and support commensurate with their job responsibilities and with ensuring the effective implementation of the provisions of this document.

These guidelines, of necessity, are neither exclusive nor all inclusive; they are, however, intended to assist management and food warehouse operators in developing and maintaining facilities, methods, practices, and controls for

the receiving, handling, storage, and shipping of foods at the food warehouse establishment in a manner that protects the public health.

They are designed to deal with exposed or otherwise uncovered foods only to the extent that such foods are exposed or uncovered during receiving, handling, storage, and shipping in the food warehouse establishment.

They are not designed to cover food manufacturing, processing, or packaging areas and related equipment, practices, and procedures which are subject to regulations and/or guidelines specifically developed for those types of operations.

If food warehousing and food manufacturing, processing, or packaging operations are maintained in the same establishment, neither type of operation should interfere with the compliance with any good sanitation practices, guidelines, or regulations applicable to the other type or types of operations.

II. Buildings and Grounds

A. *Maintain Grounds Around Warehouses in a Sanitary Manner :*

- Maintain the grounds around food warehouse buildings under the control of the operator in a well-drained condition, and free from conditions likely to lead to contamination of foods in the food warehouse, leaving the food warehouse, or being delivered to the food warehouse.
- Keep grounds clean and free of discarded equipment, lumber, litter, waste, refuse, and uncut weeds or grasses within the immediate vicinity of the food warehouse which may provide breeding places or harborages for rodents, insects and other pests.
- Locate outside waste disposal containers on properly drained areas, clean them as needed, and keep them covered between use.

• Maintain and surface driveways, truck aprons, and rail sidings at receiving and shipping areas and parking areas to facilitate good drainage and to minimize dust and dirt being blown or tracked into the food warehouse. Maintain them in a clean, well-drained condition.

• If the food warehouse buildings are closely bordered by grounds not under the operator's control, exercise special care in the food warehouse, by inspection, extermination, or other means, to exclude and control pests, dirt, and other potential contaminants originating from such non-controlled grounds.

B. *Maintain and Operate Food Warehouse Buildings and Structures in a Sanitary Manner:*

• Provide floors and interior walls which are adequately cleanable and keep them clean and in good repair.

• Suspend fixtures, ducts, and pipes which are over working areas so as to prevent drip or condensate from contaminating food or food packages.

• Maintain adequate separation by location or other effective means for those operations which may cause contamination of foods with undesirable chemicals, filth, or other extraneous material.

• Provide adequate lighting to areas where food is received, stored, held or assembled for delivery, in order to facilitate handling, processing, and examination of merchandise and to permit adequate inspection, clean-up, and repair of the buildings and their structures.

• Provide adequate lighting in hand washing areas, dressing and locker rooms (if present), and toilet rooms.

• Employ appropriate special efforts to maintain sanitation whenever necessitated by unique features of structure or design.

• In a food warehouse utilizing light bulbs, light fixtures, skylights or other glass over exposed food, such as produce items in mesh bags, etc., use safety type bulbs or shielded fixtures to prevent food contamination in case of breakage.

III. Fixtures and Equipment

• Provide food warehouse equipment which is suitable as used and maintained, and is of design, material, and workmanship which permits it to be adequately cleaned and properly maintained by the methods used at the establishment.

• Use and maintain the equipment so as to prevent the adulteration of foods with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

• Install and maintain equipment in a manner which will facilitate its cleaning and the cleaning of adjacent spaces.

IV. Sanitary Facilities

Provide the food warehouse with adequate sanitary facilities and accommodations:

A. *Water Supply:*

• From an adequate source, provide a water supply which is sufficient for the food warehouse operations.

B. *Sewage:*

• Dispose of sewage into an adequate sewerage system or through other appropriate means.

C. *Plumbing:*

• Install and maintain plumbing of adequate capacity and design and in accordance with applicable governmental sanitation requirements, if any, so as to provide sufficient

quantities of water to required locations throughout the food warehouse, and to properly convey sewage and liquid disposable waste from the food warehouse.

D. *Toilet Facilities:*

• Provide toilet facilities which are adequate, kept in good repair, conveniently located, well-ventilated, and in compliance with applicable governmental sanitation requirements, if any.

• Provide them with self-closing doors and with walls, ceilings, and floors which are tight fitting and of a material which can be easily cleaned and kept in good repair; and maintain them in a clean condition.

• Furnish toilet rooms with toilet tissue, and post signs instructing employees to wash their hands with soap or detergent before returning to work.

• If toilet rooms are located near areas in the food warehouse where exposed foods, such as produce items in mesh bags, might be subjected to airborne contamination, provide them with self-closing doors which do not open directly into such areas.

E. *Hand Washing Facilities:*

• Provide adequate hand washing facilities in the toilet rooms or in places convenient to the toilet rooms for hand washing after use of the toilets.

• Furnish such facilities with hot and cold running water, hand-cleansing soaps or detergents, sanitary towels, or other suitable drying devices.

• Provide adequate receptacles, with covers, for disposal of hand-drying articles or waste material.

• Maintain the washing facilities and the surrounding areas in a clean condition.

F. *Dressing and Locker Areas:*

• If dressing and locker areas are present, provide them with adequate ventilation and lighting, and maintain them in a clean and orderly condition.

• If lockers are present, provide them with sufficient ventilation to keep them dry for the retardation of mold and odors and maintain them in a clean condition, free from trash, food scraps, or litter which serve as insect or rodent attractants. Keep the tops of such lockers clean, and do not use them as surfaces for the storage of materials.

G. *Eating Areas:*

• If there are eating areas in the food warehouse, enclose them adequately or locate them in areas away from operations. Provide adequate space, light, and ventilation in such areas. Clean eating areas regularly, and provide them with a sufficient number of covered receptacles for disposal of meal trash. Clean such trash receptacles regularly and do not permit them to become insect or rodent attractants.

• Clean and inspect vending machines and surrounding areas at regular and frequent intervals to detect and correct conditions of insanitation which may exist in or around such machines.

• If drinking fountains are provided, locate them conveniently and clean them regularly.

V. Sanitary Operations

A. *Keep Buildings and Equipment Sanitary:*

• Maintain buildings, fixtures, equipment, and other physical facilities of the food warehouse in good repair and in a sanitary condition.

• Conduct cleaning operations in such a manner as to minimize the danger of contamination. For cleaning and

sanitizing procedures, utilize detergents, sanitizers and other supplies which are safe and effective for their intended uses.

• Exclusive of packaged products held for distribution, store and use in the food warehouse only such toxic materials as are required for necessary activities, such as for maintaining sanitary and pest free conditions, for use in laboratory testing procedures, or for food warehouse and equipment maintenance and operation. Identify and use such products only in such manner and under such conditions as will be safe for the intended use.

• Use pesticides only under such precautions and restrictions as will prevent the contamination of food and food packaging materials.

B. *Rubbish:*

• Convey, store, and dispose of rubbish in a manner which will minimize the development of odor, prevent waste from becoming an attractant and harborage or breeding place for vermin, and prevent contamination of warehoused food, food containers, ground surfaces, and water supplies.

C. *Pest Control Programs:*

• Establish and maintain positive control programs designed to exclude and eliminate pests from the food warehouse and to deny them harborage, in order to protect against the contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to, rodents and insects).

• Keep trained security dogs out of actual storage areas to avoid excreta contamination of foods stored at floor level. Keep cats out of the food warehouse.

• Implement these programs as an integral part of the construction, maintenance, operational, and personnel programs described elsewhere in the guidelines.

VI. Procedures and Controls

Conduct operations in the receiving, inspecting, transporting, handling, segregating, recouping, and storing of foods in accordance with appropriate sanitation principles. Implement overall sanitation under the supervision of an individual assigned responsibility for this function.

Take reasonable precautions, including the following, to assure that food warehouse procedures do not contribute to contamination of foods by harmful chemicals, objectionable odors, or other objectionable materials.

A. *Incoming Product Shipments:*

The integrity of the food warehouse sanitation program requires that the materials, including foods and their packaging, which are received into the warehouse do not expose the food warehouse to contamination by reason of infestation by insects, birds, rodents, or other vermin, or by introduction of filth or other contaminants. It is often useful, when practicable, to work with suppliers and shippers in advance to establish guidelines for acceptance, rejection, and where appropriate, reconditioning of particular product, taking into consideration factors such as the nature, method of shipment, and ownership of the product, in order to facilitate the effective implementation of these programs.

1. Within a reasonable time after the arrival of a car or truck, and before product is unloaded, the product should be inspected to the extent permitted by the loading of the vehicle for evidence of damage or of insect or rodent infestation, objectionable odor, or other form of contamination.

Where an adequate inspection has not been possible prior to unloading, further inspect such product during and immediately after unloading.

2. If damaged product has been accepted, keep it separate from other product, and recondition or otherwise handle it as necesary in a manner which will not expose foods or the food warehouse to contamination or infestation.

3. If the inspection reveals evidence of infestation or contamination:

• Determine whether the condition is only "suspect," or is superficial (such as surface infestation of flying insects which may be on, but have not penetrated, soiled, or compromised the integrity of the packaging) and might be fully correctable by fumigation or other means.

• In each such case, remove the product from the food warehouse area, utilizing the vehicle in which it arrived, if feasible, after closing and sealing it.

• In case of contamination, if rejection is appropriate (based on the origin and ownership of the product), promptly notify the carrier and shipper of the time, place, and circumstances of the rejection.

• After removal from the food warehouse because of suspect and/or superficial conditions, concentrated efforts can be made to further evaluate the actual condition of the product, and to recondition it, when possible.

4. Give special attention to product which has previously been rejected, or has otherwise been removed from the food warehouse because of suspect and/or superficial conditions, when it is subsequently received again, to assure that the product and packaging are fully acceptable on reinspection.

5. In the event of serious question, or of failure to agree with the shipper or carrier, as appropriate, as to condition or reconditioning, consider requesting evaluation of the suspect or rejected product by appropriate federal, state, or local authorities.

B. *Store Product Properly:*

• Place foods received into the food warehouse for handling or storage in a manner which will facilitate cleaning and the implementation of insect, rodent, and other sanitary controls and will maintain product wholesomeness.

C. *Proper Stock Rotation:*

• Adopt and implement effective procedures to provide stock rotation appropriate to the particular food.

D. *Contaminated or Damaged Foods:*

• Unless promptly and adequately repaired or corrected at or near the point of detection, promptly separate foods which are identified as being damaged or are otherwise suspect from other foods for further inspection, sorting, and disposition.

• Promptly destroy or remove from the food warehouse product determined to present a hazard of contamination to foods in the food warehouse.

E. *Hazardous Non-Food Products:*

• Handle and store non-food products which present hazards of contamination to foods stored in the same food warehouse by reason of undesirable odors, toxicity of contents, or otherwise, in a manner which will keep them from contaminating the foods.

• Take special measures to safeguard from damage and infestation those foods which are particularly susceptible to such risks.

F. *Avoid Damage to Packaging:*

• Exercise care in moving, handling and storing product to avoid damage to packaging which would affect the contents of food packages, would cause spillage, or would

otherwise contribute to the creation of insanitary conditions.

G. *Shipping:*

• Prior to loading with foods, inspect rail car and truck and trailer interiors for general cleanliness and for freedom from moisture; from foreign materials which would cause product contamination (such as broken glass, oil, toxic chemicals, etc.) or damage to packaging and contents (such as boards, nails, harmful protrusions, etc.); and from wall, floor, or ceiling defects that could contribute to insanitary conditions.

• Clean, repair, or reject them as necessary to protect foods before loading.

• Exercise care in loading foods to avoid spillage or damage to packaging and contents.

• Maintain docks, rail sidings, truck bays, and driveways free from accumulations of debris and spillage.

H. *Warehouse Temperatures:*

• Maintain warehouse temperatures (particularly for refrigerated and frozen food storage areas) which are in compliance with applicable governmental temperature requirements, if any, for maintaining the wholesomeness of the particular foods received and held in such areas.

I. *Housekeeping, Sanitation and Inspection:*

• Establish a regularly scheduled program of general housekeeping, sanitation, and inspection to maintain floors, walls, fixtures, equipment, and other physical facilities in a state of sanitation sufficient to protect foods from contamination or adulteration, and to prevent waste from becoming an attractant and harborage or breeding place for vermin.

• In addition, develop and implement an effective program and procedure for timely cleanup of any debris and spillage resulting from accidents or other unscheduled occurrences.

J. *Pest Control Measures:*

• Implement pest control measures designed to prevent the entrance of pests, to deny them harborage, and to detect and eliminate them, with such schedules, instructions, and procedures, and by such trained and qualified personnel or professional representatives as may be necessary, based on the nature of the foods and other products handled, the structure and condition of the building and equipment, and the surroundings and environment of the warehouse.

• Monitor traps and bait stations, whether inside or outside of buildings, on a regular basis. Use covered interior bait stations designed, located, or protected to prevent spillage. Where appropriate, use bait stations constructed of moistureproof material.

K. *Pesticides:*

• Use only pesticides with labels showing USDA or EPA registration numbers, and only for the uses specified in the labeling.

• Have them applied only by responsible personnel in accordance with the manufacturer's labeling instructions and in a manner which prevents contamination of foods. While not in use, clearly mark and store pesticides in a secure place apart from foods.

L. *Audit Food Warehouse Sanitation Programs:*

• Establish programs internally and/or through outside consultants for effectively auditing the food warehouse sanitation program.

VII. PERSONNEL

A. *Employee Practices:*

• Prohibit employees affected by disease in a communicable form, while carriers of such disease, or while afflicted with boils, sores, infected wounds, or other abnormal

sources of bacterial infection, from working in the food warehouse in capacities in which there is a likelihood of food becoming contaminated, or of disease being transmitted to other persons.

• Prohibit clothing or other personal belongings from being stored and food and beverages from being consumed and tobacco from being used in areas where foods are handled or stored.

• Instruct employees who are working in direct contact with exposed or partially exposed foods, such as produce items in mesh bags, etc., to maintain personal cleanliness and to conform to hygienic practices to avoid contamination of such foods with microorganisms or foreign substances such as human hair, perspiration, cosmetics, tobacco, chemicals, and medicants and, if gloves are used in handling such foods, to use only gloves which are of an impermeable material in handling such foods, and to maintain them in a clean and sanitary condition.

B. *Management Responsibilities:*

• Assign responsibility for the overall food warehouse sanitation program and authority commensurate with this responsibility to persons who, by education, training, and/or experience are able to identify sanitation risks and failures and food contamination hazards.

• Instruct employees in the sanitation and hygienic practices appropriate to their duties and the locations of their work assignments within the food warehouse. Instruct employees to report observations of infestations (such as evidence of rodents, insects or harborages) or construction defects permitting entry or harborage of pests, or other developments of insanitary conditions.

• Exercise programs of follow-up and control to ensure that your employees, consultants, and outside services are doing their jobs effectively.

Appendix

This appendix to the Voluntary Industry Sanitation Guidelines for Food Distribution Centers and Warehouses has been prepared to assist the food warehouse operator in implementation of Sections (I) through (VII) of the *Guidelines.* Information in this appendix will require adaptation for specific application to your operations.

Since no single document can provide all the information necessary for every situation or specify the only methods for compliance, develop your own appendix or company guidelines to reflect your individual applications in the general areas dealt with in the *Guidelines* and this appendix.

I. Foreword

To ensure product wholesomeness and proper sanitation, the food warehouse sanitation program must have the commitment of top management, must be implemented by operating supervision, and must be supported by the entire food warehouse staff. Preventive sanitation—the performance of inspection, sanitation, building maintenance, and pest control functions designed to prevent insanitation in preference to correcting it—should be an important goal of food warehouse management and of food warehouse operations.

II. Organization and Programs

A program to ensure continued success in safeguarding the wholesomeness of food and in providing good sanitation will ordinarily include:

1. An organizational chart showing chain of authority and responsibility.

2. A flow diagram of receiving, storage, and shipping operations.

3. Regular maintenance schedules.

4. Regular sanitation programs.

5. Regular pest control programs.

6. An effective program of follow-up and control including reports to responsible executive officer(s).

III. Check Points and Additional Guides

1. *Grounds:*

• Keep nearby grounds free of liquid or solid emissions that could be sources of contamination.

• Prevent grounds from providing conditions for insect or rodent harborage.

• Check paving, drainage, weed, and litter control regularly.

• Stack materials which are stored in the open neatly and away from buildings, and on racks above ground level where feasible.

• "No-vegetation strips" around exterior building walls and at property lines adjacent to properties containing potential harborages are helpful for discovering and discouraging travel by rodents.

2. *Buildings:*

• Provide separate and sufficient space for placement of equipment and storage of materials necessary for proper operations.

• Separate activities that might cause contamination of stored foods with chemicals, filth, or other harmful material.

• Check structural conditions, pest barriers, repair of windows, screens, and doors continuously.

• Seal and clean floor wall junctions and fill holes and cracks; a painted inspection strip is also recommended.

• Keep offices—including overhead offices—in the food warehouse clean, and do not permit them to become attractants or harborages for insects or vermin. Include them in the pest control program.

• Check false ceilings for harborage of insects and possibly rodents.

• Give basements, attics, elevators, and rail sidings, etc., special attention.

3. *Sanitary Operations:*

• Keep walls, ceilings and rafters free of soil, insect webbing, mold, and similar materials.

• Do not leave unscreened doors and windows open unnecessarily.

• Do not permit dust to accumulate.

• Keep floors free of product spillage, oil drippage, and buildup in all areas.

• Provide proper trash and refuse storage and removal.

• Store tools and equipment properly.

• Clean and flush drains regularly.

• Maintain railroad and truck courts free of debris, and properly patrol them for pest control.

• Keep eating and break areas, locker rooms, etc. clean and orderly. Vending machines are often overlooked: keep them and the areas adjacent to them clean and sanitary. Maintain equipment in a properly functioning condition and do not permit it to serve as a source of sanitation or harborage problems.

4. *Receiving and Inspection:*

• Inspect the materials which are being received for evidence of damage; insect, bird, rodent, or other vermin infestation; and moisture, odor, or chemical contamination.

• Exclude contaminated materials, including product, pallets, and slip sheets, from the building.

• If damaged merchandise is accepted, segregate it for special handling.

• Make sure that incoming and outgoing vehicles are free of conditions that could contaminate product—no birds, rodents, insects, spillage, or objectionable odor should be evident.

• Code or mark foods received at the receiving point to ensure proper stock rotation.

• To facilitate handling of rejected and suspect product, it is often a good idea to develop procedures with individual shippers, carriers, and/or manufacturers for reinspections, returns, etc.

5. *Storage:*

• Store products in an orderly manner and so that date codes are visible for proper rotation.

• Generally, it is desirable to stack foods on pallets or racks (or on slip sheets, where a clamp truck operation is utilized), and away from walls so as to allow for inspection aisles between stacks and walls. Painting inspection aisles in a light color is often helpful in maintaining their effectiveness. Where full inspection aisles are not provided, take special care (such as more frequent inspection, rotation, and removal of product for cleaning) to ensure sanitary, pest free conditions.

• Separate bagged and baled foods to provide visibility between stacks.

• Dispose of contaminated or infested merchandise, or otherwise remove it from the food warehouse promptly.

• Promptly remove damaged merchandise and broken containers from general food storage areas. Handle and process salvageable merchandise separately in an area isolated from general food storage; this area probably will require extra sanitation and pest control attention.

• If salvage operations include the repackaging or other manipulation of exposed foods (other than items such as fresh produce received unpackaged or in partially open packages), conduct such operations in compliance with the food sanitation practices, guidelines, or regulations, such as 21 CFR 128, which are applicable to handling exposed foods.

• Do not intermingle chemicals, including pesticides, with food or food products. Such products are best separated by an aisleway.

6. *Pest Control:*

• Maintain written schedules, log activity, and monitor traps and bait stations regularly.

• Use covered bait stations which are of such types and so located as to reduce the danger of spoilage; and where appropriate, use moisture-proof bait stations.

• Keep the pesticides which are used in the food warehouse securely, and separate from foods. Permit their use only by properly trained personnel. Use only types registered and approved by an appropriate government agency for the intended use.

• Check especially for:

  • rodent burrows in nearby grounds,

  • activity at floor wall junctions and doorways, and

- insect crawl marks in dust accumulation, especially on overhead pipes, beams, window sills, around flour, sugar, and pet food storage.

• Where feasible, seal load levelers at docks to prevent trash accumulations and rodent harborage and entry; and clean them frequently.

• Look for insect activity in folds of bagged foods.

• Use black light, supplemented with means for distinguishing other chemicals that fluoresce, to check for rodent urine stains; and use flashlights to check for other evidence of contamination.

7. *Shipping:*

• Make sure that transportation equipment into which food warehouse food is loaded is maintained in a sanitary condition comparable to that of the food warehouse.

• Make sure that rail cars, trailers and trucks . . . are free of birds, rodents and insects or contamination from them,

. . . are free of odors, nails, splinters, oil, and grease,

. . . are free of accumulations of dirt or dunnage, and

. . . are in good repair and have no holes, cracks, or crevices that could provide entrances or harborages for pests.

8. *Follow-Up:*

8 Exercise programs of follow-up and control to ensure that your employees, consultants, and outside services are doing their jobs effectively.

REPRINT OF PART 128, TITLE 21 OF FEDERAL REGULATIONS

PART 128—HUMAN FOODS; CURRENT GOOD MANUFACTURING PRACTICE (SANITATION) IN MANUFACTURE, PROCESSING, OR HOLDING

Sec.

128.1 Definitions.
128.2 Current good manufacturing practice (sanitation).
128.3 Plant and grounds.
128.4 Equipment and utensils.
128.5 Sanitary facilities and controls.
128.6 Sanitary operations.
128.7 Processes and controls.
128.8 Personnel.
128.9 Exclusions.
128.10 Natural or unavoidable defects in food for human use that present no health hazard.

AUTHORITY: The provisions of this Part 128 issued under secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a)(4), 371(a) unless otherwise noted.

SOURCE: The provisions of this Part 128 appear at 34 FR 6977, Apr. 26, 1969, unless otherwise noted.

§ 128.1 Definitions.

The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part. The following definitions shall also apply:

(a "Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(b) "Plant" means the building or buildings or parts thereof, used for or in connection with the manufacturing, processing, packaging, labeling, or holding of human food.

(c) "Sanitize" means adequate treatment of surfaces by a process that is effective in destroying vegetative cells of pathogenic bacteria and in substantially reducing other micro-organisms. Such treatment shall not adversely affect the product and shall be safe for the consumer.

§ 128.2 Current good manufacturing practice (sanitation).

The criteria in §§ 128.3 through 128.8 shall apply in determining whether the facilities, methods, practices, and controls used in the manufacture, processing, packing, or holding food are in conformance with or are operated or administered in conformity with good manufacturing practices to assure that food for human consumption is safe and has been prepared, packed, and held under sanitary conditions.

§ 128.3 Plant and grounds.

(a) *Grounds.* The grounds about a food plant under the control of the operator shall be free from conditions which may result in the contamination of food including, but not limited to, the following:

(1) Improperly stored equipment, litter, waste, refuse, and uncut weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for rodents, insects, and other pests.

(2) Excessively dusty roads, yards, or parking lots that may constitute a source of contamination in areas where food is exposed.

(3) Inadequately drained areas that may contribute contamination to food products through seepage or foot-borne filth and by providing a breeding place for insects or micro-organisms.

If the plant grounds are bordered by grounds not under the operator's control of the kind described in subparagraphs (1) through (3) of this paragraph, care must be exercised in the plant by inspection, extermination, or other means to effect exclusion of pests, dirt, and other filth that may be a source of food contamination.

(b) *Plant construction and design.* Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-processing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for sanitary operations and production of safe food. Floors, walls, and ceilings in the plant shall be of such construction as to be adequately cleanable and shall be kept clean and in good repair. Fixtures, ducts, and pipes shall not be so suspended over working areas that drip or condensate may contaminate foods, raw materials, or food-contact surfaces. Aisles or working spaces between equipment and between equipment and walls shall be unobstructed and of sufficient width to permit employees to perform their duties without contaminaton of food or food-contact surfaces with clothing or personal contact.

(2) Provide separation by partition, location, or other effective means for those operations which may cause contamination of food products with undesirable micro-organisms, chemicals, filth, or other extraneous material.

(3) Provide adequate lighting to hand-washing areas, dressing and locker rooms, and toilet rooms and to all areas where food or food ingredients are examined, processed, or stored and where equipment and utensils are cleaned. Light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation shall be of the safety type or otherwise protected to prevent food contamination in case of breakage.

(4) Provide adequate ventilation or control equipment to minimize odors and noxious fumes or vapors (including steam) in areas where they may contaminate food. Such ventilation or control equipment shall not create conditions that may contribute to food contamination by airborne contaminants.

(5) Provide, where necessary, effective screening or other protection against birds, animals, and vermin (including, but not limited to, insects and rodents)

§ 128.4 Equipment and utensils.

(a) *General.* All plant equipment and utensils should be (1) suitable for their intended use, (2) so designed and of such material and workmanship as to be adequately cleanable, and (3) properly maintained. The design, construction, and use of such equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.

(b) *Use of polychlorinated biphenyls in food plants.* Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and non-flammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment and causing the contamination of certain foods. In addition, incidents

have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn cause the contamination of food intended for human consumption (meat, milk, and eggs). Since PCB's are toxic chemicals, the PCB contamination of food as a result of these accidents represents a hazard to human health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in the production, handling, and storage of food. The following special provisions are necessary to preclude accidental PCB contamination of food:

(1) New equipment, utensils, and machinery for handling or processing food in or around a food plant shall not contain PCB's.

(2) On or before September 4, 1973, the management of food plants shall:

(i) Have the heat exchange fluid used in existing equipment or machinery for handling or processing food sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must be replaced with a heat exchange fluid that does not include PCB's.

(ii) Eliminate from the food plant any PCB-containing food-contact surfaces of equipment or utensils and any PCB-containing lubricants for equipment or machinery that is used for handling or processing food.

(iii) Eliminate from the food plant any other PCB-containing materials wherever there is a reasonable expectation that such materials could cause food to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iv) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately de-

termined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to (*a*) its toxicity; (*b*) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (*c*) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (*d*) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently non-hazardous is to be made on an individual installation and operation basis.

(3) For the purposes of this section, the provisions do not apply to electrical transformers and condensers containing PCB's in sealed containers.
[38 FR 18012, July 6, 1973]

§ 128.5 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to, the following:

(a) *Water supply.* The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts foods or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature and under pressure as needed shall be provided in all areas where the processing of food, the cleaning of equipment utensils, or containers, or employee sanitary facilities require.

(b) *Sewage disposal.* Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(c) *Plumbing.* Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Not constitute a source of contamination to foods, food products or ingredients, water supplies, equipment or utensils or create an insanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flood-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(d) *Toilet facilities.* Each plant shall provide its employees with adequate toilet and associated hand-washing facilities within the plant. Toilet rooms shall be furnished with toilet tissue. The facilities shall be maintained in a sanitary condition and kept in good repair at all times. Doors to toilet rooms shall be self-closing and shall not open directly into areas where food is exposed to airborne contamination, except where alternate means have been taken to prevent such contamination (such as double doors, positive air-flow systems, etc.). Signs shall be posted directing employees to wash their hands with cleaning soap or detergents after using toilet.

(e) *Hand-washing facilities.* Adequate and convenient facilities for hand washing and, where appropriate, hand sanitizing shall be provided at each location in the plant where good sanitary practices require employees to wash or sanitize and dry their hands. Such facilities shall be furnished with running water at a suitable temperature for hand washing, effective hand-cleaning and sanitizing preparations, sanitary towel service or suitable drying devices, and, where appropriate, easily cleanable waste receptacles.

(f) *Rubbish and offal disposal.* Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, prevent waste from becoming an

attractant and harborage or breeding place for vermin, and prevent contamination of food, food-contact surfaces, ground surfaces, and water supplies.

§ 128.6 Sanitary operations.

(a) *General maintenance.* Buildings, fixtures, and other physical facilities of the plant shall be kept in good repair and shall be maintained in a sanitary condition. Cleaning operations shall be conducted in such a manner as to minimize the danger of contamination of food and food-contact surfaces. Detergents, sanitizers, and other supplies employed in cleaning and sanitizing procedures shall be free of significant microbiological contamination and shall be safe and effective for their intended uses. Only such toxic materials as are required to maintain sanitary conditions, for use in laboratory testing procedures, for plant and equipment maintenance and operation, or in manufacturing or processing operations shall be used or stored in the plant. These materials shall be identified and used only in such manner and under conditions as will be safe for their intended uses.

(b) *Animal and vermin control.* No animals or birds, other than those essential as raw material, shall be allowed in any area of a food plant. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to, rodents and insects). The use of insecticides or rodenticides is permitted only under such precautions and restrictions as will prevent the contamination of food or packaging materials with illegal residues.

(c) *Sanitation of equipment and utensils.* All utensils and product-contact surfaces of equipment shall be cleaned as frequently as necessary to prevent contamination of food and food products. Nonproduct-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to minimize accumulation of

dust, dirt, food particles, and other debris. Single-service articles (such as utensils intended for one-time use, paper cups, paper towels, etc.) should be stored in appropriate containers and handled, dispensed, used, and disposed of in a manner that prevents contamination of food or food-contact surfaces. Where necessary to prevent the introduction of undesirable microbiological organisms into food products, all utensils and product-contact surfaces of equipment used in the plant shall be cleaned and sanitized prior to such use and following any interruption during which such utensils and contact surfaces may have become contaminated. Where such equipment and utensils are used in a continuous production operation, the contact surfaces of such equipment and utensils shall be cleaned and sanitized on a predetermined schedule using adequate methods for cleaning and sanitizing. Sanitizing agents shall be effective and safe under conditions of use. Any facility, procedure, machine, or device may be acceptable for cleaning and sanitizing equipment and utensils if it is established that such facility, procedure, machine, or device will routinely render equipment and utensils clean and provide adequate sanitizing treatment.

(d) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment and utensils with product-contact surfaces should be stored in such a location and manner that product-contact surfaces are protected from splash, dust, and other contamination.

§ 128.7 Processes and controls.

All operations in the receiving, inspecting, transporting, packaging, segregating, preparing, processing, and storing of food shall be conducted in accord with adequate sanitation principles. Overall sanitation of the plant shall be under the supervision of an individual assigned responsibility for this function. All reasonable precautions, including the following, shall be taken to assure that produc-

tion procedures do not contribute contamination such as filth, harmful chemicals, undesirable micro-organisms, or any other objectionable material to the processed product:

(a) Raw material and ingredients shall be inspected and segregated as necessary to assure that they are clean, wholesome, and fit for processing into human food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as required to remove soil or other contamination. Water used for washing, rinsing, or conveying of food products shall be of adequate quality, and water shall not be reused for washing, rinsing, or conveying products in a manner that may result in contamination of food products.

(b) Containers and carriers of raw ingredients should be inspected on receipt to assure that their condition has not contributed to the contamination or deterioration of the products.

(c) When ice is used in contact with food products, it shall be made from potable water and shall be used only if it has been manufactured in accordance with adequate standards and stored, transported, and handled in a sanitary manner.

(d) Food-processing areas and equipment used for processing human food should not be used to process non-human food-grade animal feed or inedible products unless there is no reasonable possibility for the contamination of the human food.

(e) Processing equipment shall be maintained in a sanitary condition through frequent cleaning including sanitization where indicated. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(f) All food processing, including packaging and storage, should be conducted under such conditions and controls as are necessary to minimize the potential for undesirable bacterial or other microbiological growth, toxin formation, or deterioration or contamination of the processed product or ingredients. This may require careful monitoring of such physical factors as time, temperature, humidity, pressure, flow-rate and such processing operations as freezing, dehydration, heat processing, and refrigeration to assure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of the processed products.

(g) Chemical, microbiological, or extraneous-material testing procedures shall be utilized where necessary to identify sanitation failures or food contamination, and all foods and ingredients that have become contaminated shall be rejected or treated or processed to eliminate the contamination where this may be properly accomplished.

(h) Packaging processes and materials shall not transmit contaminants or objectionable substances to the products, shall conform to any applicable food additive regulation (Part 121 of this chapter), and should provide adequate protection from contamination.

(i) Meaningful coding of products sold or otherwise distributed from a manufacturing, processing, packing, or repacking activity should be utilized to enable positive lot identification to facilitate, where necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use. Records should be retained for a period of time that exceeds the shelf life of the product, except that they need not be retained more than 2 years.

(j) Storage and transportation of finished products should be under such conditions as will prevent contamination, including development of pathogenic or toxigenic micro-organisms, and will protect against undesirable deterioration of the product and the container.

§ 128.8 Personnel.

The plant management shall take all reasonable measures and precautions to assure the following:

(a) *Disease control.* No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological contamination, shall work in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by such person, or of disease being transmitted by such person to other individuals.

(b) *Cleanliness.* All persons, while working in direct contact with food preparation, food ingredients, or surfaces coming into contact therewith shall:

(1) Wear clean outer garments, maintain a high degree of personal cleanliness, and conform to hygienic practices while on duty, to the extent necessary to prevent contamination of food products.

(2) Wash their hands thoroughly (and sanitize if necessary to prevent contamination by undesirable microorganism) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(3) Remove all insecure jewelry and, during periods where food is manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized.

(4) If gloves are used in food handling, maintain them in an intact, clean, and sanitary condition. Such gloves should be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

(5) Wear hair nets, headbands, caps, or other effective hair restraints.

(6) Not store clothing or other personal belongings, eat food or drink beverages, or use tobacco in any form in

areas where food or food ingredients are expose or in areas used for washing equipment or utensils.

(7) Take any other necessary precautions to prevent contamination of foods with micro-organisms or foreign substances including, but not limited to perspiration, hair, cosmetics, tobacco, chemicals, and medicants.

(c) *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of education, or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food-handling techniques and food-protection principles and should be cognizant of the danger of poor personal hygiene and insanitary practices.

(d) *Supervision.* Responsibility for assuring compliance by all personnel with all requirements of this Part 128 shall be clearly assigned to competent supervisory personnel.

§ 128.9 Exclusions.

The following operations are excluded from coverage under these general regulations, however, the Commissioner will issue special regulations when he believes it necessary to cover these excluded operations: Establishments engaged solely in the harvesting, storage, or distribution of one or more raw agricultural commodities, as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated or otherwise processed before being marketed to the consuming public.

§ 128.10 Natural or unavoidable defects in food for human use that present no health hazard.

(a) Some foods, even when produced under current good manufacturing and/or processing practices, contain natural or unavoidable defects at lower levels that are not

hazardous to health. The Food and Drug Administration establishes maximum levels for such defects in foods produced under good manufacturing and/or processing practices and uses these levels for recommending regulatory actions.

(b) Defect action levels are established for products whenever it is necessary and feasible. Such levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse failure to observe either the requirement in section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this part that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection indicating such a violation renders the food unlawful, even though the amounts of natural or unavoidable defects are lower than the currently established action levels. The manufacturer of food must at all times utilize quality control procedures which will reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food unlawful regardless of the defect level of the final food.

(e) Current action levels for natural and unavoidable defects in food for human use that present no health hazard are as follows. (Levels that have been adopted on a temporary basis prior to publication as a regulation may be obtained upon request at the Office of the Assistant Commissioner for Public Affairs, Food and Drug Administration, Room 15B-42, 5600 Fishers Lane, Rockville, Md. 20852.)

[38 F.R. 855, Jan. 5, 1973]